U.S. Department of Justice
Civil Division, Consumer Protection Branch

Hilary K. Perkins
Trial Attorney

Hilary.K.Perkins@usdoj.gov
(202) 307-0052

June 18, 2020

VIA ECF

Hon. Theodore D. Chuang
U.S. District Court for the District of Maryland
6500 Cherrywood Lane, Suite 245A
Greenbelt, MD 20770

Re: *American College of Obstetricians and Gynecologists et al. v. U.S. Food and Drug Administration et al.*, No. 8:20-cv-1320-TDC (D. Md.)

Dear Judge Chuang:

Defendants respectfully submit this letter to clarify a point made in their Memorandum in Opposition to Plaintiffs' Motion for a Preliminary Injunction, Docket No. 62 (filed June 10, 2020).

On page 10, the Opposition stated that "drug sponsors, not plaintiffs, . . . bear the responsibility for ensuring compliance with the ETASU requirements," and that "Plaintiffs face no direct penalties stemming from an enforcement action by FDA." Doc. 62 at 10. Those statements reflect the fact that plaintiffs have not alleged that they engage in, or intend to engage in, interstate activity that could conceivably violate 21 U.S.C. § 355(p). *See* 21 U.S.C. § 355(p) (making it unlawful to "introduce or deliver for introduction *into interstate commerce* a new drug" while "fail[ing] to maintain compliance" with the ETASU requirements) (emphasis added).

To avoid any confusion, the government wishes to clarify that in a different case where a drug was introduced or delivered for introduction into interstate commerce by a physician, it is possible that FDA might interpret 21 U.S.C. § 355(p) to authorize an enforcement action against that physician. *See* 21 U.S.C. §§ 331, 333. FDA has never taken enforcement action against a physician under section 355(p), however, and has not had occasion to take a position on whether and how section 355(p) might apply to a physician who actually introduced or delivered for introduction into interstate commerce a new drug. But regardless of how such a hypothetical case might be resolved, it is clear that here, where plaintiff physicians do not allege that they intend to introduce a new drug into interstate commerce or deliver a new drug for such introduction, plaintiffs would not be subject to enforcement actions themselves, nor would they be subject to penalties imposed by the government as a result of any enforcement action against a drug sponsor.

Defendants thank the Court for its attention to this matter.

Very truly yours,

GUSTAV W. EYLER
Director
Consumer Protection Branch
Civil Division

By: */s/ Hilary K. Perkins*
Hilary K. Perkins
Trial Attorney
Consumer Protection Branch

cc (via CM/ECF):
Counsel of Record

CERTIFICATE OF SERVICE

I certify that on June 18, 2020, I served a copy of this correspondence by filing it with the Court's CM/ECF system, which transmits a copy to all registered parties.

/s/ Hilary K. Perkins
Hilary K. Perkins
Trial Attorney
Consumer Protection Branch